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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,787	05/23/2006	Jonathan Michael Blackburn	40418-509N01US	3797

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1657	

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05/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,787	BLACKBURN ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-54,56 and 58-66* is/are pending in the application.

4a) Of the above claim(s) *60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-54,56,58,59 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2/10, 11/24/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment and IDS received 4/2/10, and the IDS received 11/24/09 have been entered and claims 37-54, 56, 58-59, 61-66 are considered here. Please update the continuing information in the preamble of the specification.

In view of the amendments to the claims and arguments presented, the rejections of record under 35 USC 102(b) and 112, second paragraph, are hereby withdrawn. The amended title is acceptable.

Although not claimed, it appears the point of novelty of the invention as described in the specification resides in the polyethylene glycol coating to repel protein on the probe surface. See paragraph 58 in the present specification. Further, some of the dependent claims are directed to a specific buffer as discussed in paragraph 28 of the present specification. All the rest of the claimed features are well known in Maldi technology and are not considered here further.

Newly submitted amendments to the claims directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The addition of "or the activity of a G-protein coupled receptor" is a distinct species from the previously claimed "enzyme activity".

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the species of "or the activity of a G-protein coupled receptor" is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-54, 56, 57-59, 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wagner in view of Kolster.

Wagner (WO 00/04382) entitled "Arrays of Proteins and Methods of Use Thereof' teaches on page 12, on the probe there is an organic thin film of polyethylene glycol which reduces the non-specific binding of molecules to the surface. Exposed functionalities serve to tether the thin film to the surface of the substrate or the coating. Other functions of the coating are discussed. On page 32 last paragraph affinity tags with a given functionality on the organic thin film are discussed.

The invention differs from Wagner in that the buffer selected is ammonium carbonate.

Kolster (6,258,538) entitled "DNA Diagnostics Based on Mass Spectrometry" teaches conventional Maldi in a number of standard applications. In column 19 line 52 ammonium carbonate buffer is shown on a mass spec platform.

It would have been obvious to one of ordinary skill in this art at the time of the invention to perform standard Maldi analysis as shown by each of the above references with a volatile buffer such as ammonium carbonate as shown by Kolster because no buffer residue would be left on the probe when dried. Employing a known buffer for its known function with the expected results would have been obvious.

Applicant's arguments filed 4/2/10 have been fully considered but they are not persuasive.

Applicants response argues that the invention is directed to a label free detection system to interrogate enzymatic reactions. Wagner is directed to antibody binding and not to enzyme mediated catalysis or mass spec probes. Kolster does not teach determining activity of an enzyme with mass spec.

It is the examiner's position that Wagner teaches on page 12 the function of the thin film is to enable certain detection techniques to be used with the surface and prevent inactivation of protein immobilized on the surface. On page 17 last paragraph the proteins immobilized on the surface include enzymes, examples are kinases, phosphatases, hydrolases. On page 46 non-label detection methods are generally preferred. On page 48 enzyme substrate interactions are studied and the interaction may involve catalysis. Kolster teaches conventional MALDI including mass spec probes which includes the steps of (i) – (v) as seen in present claim 37 which are all conventional MALDI steps but not the protein repellent compound layer. The present claims are not directed to a label free detection system.

Claims 37-54, 56, 58-59, 61-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyethylene glycol bound with a poly amino acid, does not reasonably provide enablement for a layer resistant to non-specific protein binding comprising protein repellent molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 37 the terms "a layer resistant to non-specific protein binding comprising protein repellent molecules" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such layer would work in the instant invention.

On page 12 of the present specification first paragraph, the protein repellent molecules are described in connection with binding moieties as related to the enzyme being tested. This is an essential feature of the claimed invention.

The number of required characteristics of the claimed layer is considerable beyond repelling proteins and one of skill in this art would not know what compounds would meet such characteristics.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of compounds.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's arguments filed 4/2/10 have been fully considered but they are not persuasive.

Applicants response argues that the coating is described in paragraph 60 of the specification which teaches how to make the coating.

It is the examiner's position that the description provided in the specification for the coating, which is the singular point of novelty of the claimed invention, is only broadly described and insufficient for one of skill in this art to make and use the invention. For example, polyethylene glycol with a functional group that may be attached via a linker encompasses a plethora of different compounds, most of which will not work in the claimed invention. The rejection is not based on how to make the coating but on what the material of the coating is made of.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

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